

### REMARKS/ARGUMENT

Applicants gratefully acknowledge the withdrawal of the 103(a) rejections in response to the Amendment filed November 25, 2008.

Claims 35 and 40-43 stand rejected under 35 U.S.C. 112, second paragraph as being indefinite for reciting the term "about." In response, those claims have been amended to remove the term.

Claims 22-26, 30, 34-37, and 39-43 stand rejected under 35 U.S.C. 102(a) or 102(e) as being anticipated by Babcock et al. US 2001/0053791 A1 (Babcock). This rejection is respectfully traversed for the following reasons.

The claimed invention is directed to solid amorphous dispersions comprising a drug in a concentration-enhancing polymer. Such dispersions represent an improvement in formation of solid amorphous dispersions relative to the prior art in that the particles produced by the process have a larger size and a reduced proportion of fines (that is, a reduced number of small particles), while still providing enhanced dissolved drug concentration for low-solubility drugs (see page 2, line 33 to page 3, line 18 of the as-filed application). As recited in the only remaining independent claim 22, the average diameter of the particles is at least 40  $\mu\text{m}$ , and at least 80 vol% of the particles have diameters greater than 10  $\mu\text{m}$ .

While the Examiner is correct that Babcock discloses solid amorphous dispersions of a drug and a concentration-enhancing polymer, Babcock's dispersions do not comprise particles with average diameters that are at least 40  $\mu\text{m}$  with at least 80 vol% of the particles having diameters greater than 10  $\mu\text{m}$ . Rather, Babcock broadly

discloses that the solid amorphous dispersion particles that can range from 1 to 200  $\mu\text{m}$ . Babcock, paragraph [0063]. Babcock also teaches that "In many cases, spray-drying conditions are chosen that require the droplets be less than about 20 to 50  $\mu\text{m}$  in diameter," *Ibid*, paragraph [0082], and that suitable nozzles for forming the droplets include fountain nozzles, flat-fan nozzles, and two-fluid nozzles. *Ibid*. The Examiner is reminded that a prior art reference is to be taken as a whole, including portions that teach away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 USPQ 303 (Fed Cir 1983).

The Examiner's attention is further directed to the fact that Drug A in Babcock corresponds to Drug 2 in the instant application. Example 3 of the instant application shows the preparation of a dispersion of 50 wt% drug and 50 wt% HPMCAS, which is the same composition as Example 2 of Babcock. Example 2 of Babcock was made using a two-fluid external mix spray nozzle, whereas Example 3 of the instant application was made using a pressure nozzle. See the published application US 2004/0194338 at paragraphs [0150] and [0123]. The same dispersion of 50 wt% drug and 50 wt% HPMCAS was made as Control C2 using a two-fluid nozzle in the instant application. *Ibid* at paragraph [0153]. The sizes of the particles produced by the use of a pressure nozzle (Example 3) and a two-fluid nozzle (Control C2) were then measured and are set out in Table 9. *Ibid* at paragraphs [0154]–[0155]. As shown in Table 9 of the instant application, the Control C2 composition that is the same composition as Example 2 of Babcock, had an average particle diameter of 20  $\mu\text{m}$ , which is one-half the minimum average particle diameter of 40  $\mu\text{m}$  recited in independent claim 22. Based on this, it is submitted that a *prima facie* showing has been made that claim 22 is not

anticipated by Babcock since the claimed invention is not identically disclosed in Babcock, which is required for anticipation. *Richardson v. Suzuki Motor Co.*, 9 USPQ 2d 1913, 1920 (Fed Cir 1989). Since the remaining claims all ultimately depend from claim 22, they too are not anticipated by Babcock.

Claims 22-26, 30, 34-37, and 39-43 stand rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-25 of U.S. Patent No. 6,973,741 (the '741 patent). Filed herewith is a terminal disclaimer which overcomes the double patenting rejection.

Respectfully submitted,

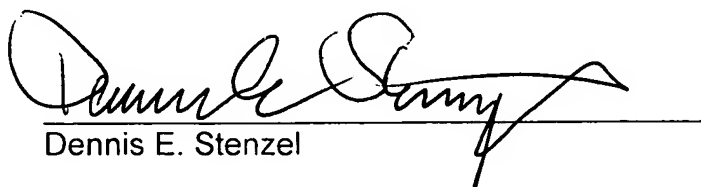


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